November 9, 2006

DEC - 5 2006

510k Summary

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the HD Digital Camera System 510(k) Number K063457.

A. Submitter

ConMed Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Elizabeth Paul
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name:	TrueHD (1080P) Digital Camera System
Common Name:	HD Digital Camera System
Classification Name:	Laparoscope, General & Plastic Surgery Endoscope and Accessories
Proposed Class:	Class II
Device Product Code:	GCJ

510k Summary
HD Digital Camera System
510(k) # K063457
November 9, 2006

D. Predicate/Legally Marketed Device

Linvatec Corporation
3-CCD Digital Camera System
510(k) K031098

E. Device Description

The device description of the modified device is identical to the legally marketed, unmodified device (510(k) K031098) with the exception that the modified device enables high definition visualization.

Modified Device

The ConMed Linvatec HD Digital Camera System consists of a camera control unit and a camera head that is used in conjunction with an endoscope to allow for high definition visualization during minimally invasive surgical procedures. Like the unmodified device, sterilization of the camera head and cable is required before use. Additionally, the camera heads may be sterilized using steam sterilization like the unmodified device.

The ConMed Linvatec HD Digital Camera System will be capable of interfacing with the ConMed I.S. Operating Room Control System with no impact on normal camera system operation.

Unmodified Device (reference)

The ConMed Linvatec Digital Camera System consists of a camera control unit and a camera head that is used in conjunction with an endoscope to allow for visualization during minimally invasive surgical procedures. Sterilization of the camera head and cable is required before use. The camera heads may be sterilized using steam sterilization.

The ConMed Linvatec 3-CCD HD Digital Camera System will be capable of interfacing with the ConMed I.S. Operating Room Control System with no impact on normal camera system operation.

F. Intended Use

Note: The device description of the modified device is identical to the legally marketed, unmodified device (510(k) K031098).

The ConMed Linvatec HD Digital Camera System is intended for endoscopic camera use in a variety of endoscopic surgical procedures including orthopedic, laparoscopic, urologic, sinuscopic, plastic and as an accessory for microscopic surgery. Sterilization of the camera head and cable is required before use. The ConMed Linvatec HD Digital Camera System will be capable of interfacing with a remote controlled operating system, Linvatec Light Source (K031994) with no impact on normal camera system operation.

G. Substantial Equivalence

The modifications to the legally marketed device in the HD Digital Camera System do not affect the intended use nor alter the fundamental scientific technology of the device. In addition, the modified device is substantially equivalent in materials, design and sterilization requirements to the unmodified device. The device modifications do not introduce any new issues of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ConMed Linvatec Corporation
% Ms. Elizabeth Paul
Manager, Regulatory Affairs
11311 Concept Boulevard
Largo, Florida 33773-4908

DEC - 5 2006

Re: K063457
Trade/Device Name: HD Digital Camera System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: November 9, 2006
Received: November 16, 2006

Dear Ms. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

November 9, 2006

510(k) Number (if known): K063457

Device Name: HD Digital Camera System

Indications For Use:

The ConMed Linvatec HD Digital Camera System is intended for use in a variety of endoscopic surgical procedures including but not limited to orthopedic, laparoscopic, urologic, sinuscopic, plastic and as an accessory for microscopic surgery.

Note: The indications for use of the modified device is identical to the legally marketed, unmodified device (510(k) K031098).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063457